REMARKS

The present invention relates to the stabilization of thrombin and to the measurement of fibrinogen concentration.

In the Office Action of October 20, 2005, claims 47, 49, 55 and 57 were rejected under 35 U.S.C. § 103(a) based on JP 61171429 (JP '429) taken with Stout et al. Claims 47, 49, 55, and 57 were also rejected under §103(a) based on the Lemole reference taken with Yamamoto. There were no other rejections.

In the present Amendment, Applicants have rewritten the claims as claims 63-70, including independent claims 63 and 68, and have canceled claims 47, 49, 55, and 57, to place the claims in more appropriate form to more clearly show the distinctions between the present invention and the cited prior art. Applicants respectfully submit that claims 63-70 clearly distinguish over the cited references, and are unobvious and patentable, for the reasons as set forth in more detail below.

II. Argument

(i) Independent claim 63:

Claim rejections under USC 103(a)

JP61-171429 describes an agent for regenerating tissue damaged by disease or surgery. It is disclosed in the JP '429 document that the agent comprises fibrinogen, thrombin and calcium

chloride.

Stout et al (U.S. Patent 4,330,551) describes a method for treating patients by a therapeutic composition being effective in relieving pain and in regeneration of tissue. It is disclosed in Stout et al that the therapeutic composition comprises cationic surfactant, nonionic surfactant, and water.

However, there is no description in JP61-171429 nor in Stout about the following steps which are the constituent feature of claim 63 of the present application:

1) mixing a sample and a reagent comprising thrombin, calcium ion, water-soluble organic acid and nonionic surfactant; and

2) measuring a coagulation time of the mixture of the sample and the reagent.

Therefore, the present invention in accordance with independent claim 63 and dependent claims 64-67 herein is not obvious from the disclosures of JP61-171429 or Stout.

Lemole (U.S. Patent 4,637,815) describes a method for reducing mediastinal fibrinolysis in open heart surgery patients and a hemostatic agent used for the method. It is disclosed that the agent comprises calcium chloride, epsilon-aminocaproic acid and thrombin.

Yamamoto (U.S. Patent 4,395,398) describes a dental hemostatic composition used for

small hemorrhage in the mouth. It is disclosed in Yamamoto that the composition comprises one or more surfactants selected from the group consisting of cationic surfactants, anionic surfactants and nonionic surfactants.

However, there is no description in Lemole nor in Yamamoto about the following steps which are the constituent feature of claim 63 of the present application:

1) mixing a sample and a reagent comprising thrombin, calcium ion, water-soluble organic acid and nonionic surfactant; and

2) measuring a coagulation time of the mixture of the sample and the reagent.

Therefore, the present invention in accordance with independent claim 63 and dependent claims 64-67 herein is not obvious from the disclosures of Lemole and Yamamoto.

(ii) Independent claim 68

Claim rejections under USC 103(a):

JP61-171429 describes an agent for regenerating tissue damaged by disease or surgery, as was noted above. It is disclosed in the JP '429 document that the agent comprises fibrinogen, thrombin and calcium chloride. Stout et al, *supra* describes a method for treating patients by a therapeutic composition being effective in relieving pain and in regeneration of tissue. It is disclosed in Stout et al that the therapeutic composition comprises cationic surfactant, nonionic surfactant, and water.

However, there is no description in JP61-171429 nor in Stout about stabilizing thrombin by using a calcium ion, a water-soluble organic acid and a nonionic surfactant, which are constituent features of claim 68 of the present application.

Therefore, the invention of independent claim 68 and dependent claims 69-70 of the present application is not obvious from the disclosures of JP61-171429 nor Stout et al.

Lemole *supra* describes a method for reducing mediastinal fibrinolysis in open heart surgery patients and a hemostatic agent used for the method. It is disclosed that the agent comprises calcium chloride, epsilon-aminocaproic acid and thrombin.

Yamamoto, *supra* describes a dental hemostatic composition used for small hemorrhage in the mouth. It is disclosed in Yamamotot that the composition comprises one or more surfactants selected from the group consisting of cationic surfactants, anionic surfactants and nonionic surfactants.

However, there is no description in Lemole nor in Yamamoto about stabilizing thrombin by using a calcium ion, a water-soluble organic acid and a nonionic surfactant which are the required features of claim 68 of the present application.

In view of the foregoing, it is respectfully submitted that the invention of independent

claim 68 and dependent claims 69-70 of the application is not obvious from the disclosures of Lemole nor Yamamoto.

In view of the above, reconsideration and allowance of now pending claims 63-70 of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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